No. 31015/5/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: **The review application of M/s Wockhardt Ltd dated 05/04/2016 under para 31 of DPCO against NPPA order No. S.O. 1254(E) dated 29/03/2016 for price fixation of Methyldopa Tablet 500mg.**

Ref: **1) Review application dated 05.04.2016**
2) NPPA notification under review S.O. No.1254(E) dated 29.3.2016
3) Record Note of discussions held in the personal hearings held in the matter on 29.4.2016, 31.5.2016 and 18.10.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Wockhardt. Ltd. (hereinafter called the petitioner) against notification S.O. No.1254(E) dated 29.03.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Methyldopa Tablet 500 mg.

2. The petitioner has contended as under:

(i) The product of Methyldopa 500 mg Tablets is a non-scheduled formulation as per NLEM 2011 under DPCO, 2013. The product is added in schedule I as per new list of NLEM 2015;

(ii) The price is fixed under Para 15 as a new drug for existing manufacturers of scheduled formulation. Our product does not fall within the ambit or provision of para 2 (u) of the DPCO, 2013;

(iii) Wockhardt has neither manufactured or imported or marketed scheduled formulation of Methyldopa of any strength or dose including 250 mg which is a schedule formulation as per DPCO, 2013 at the time of introducing 500 mg tablets in the market.

(iv) From a combined reading of the statutory provisions, they concluded as under:

- Wockhardt was neither a manufacturer nor an importer nor a marketer for Methyldopa 250 mg at any point of time when DPCO, 2013 came into effect.

- Wockhardt was not even an existing manufacturer of the drug Methyldopa in any strength or dosage when DPCO, 2013 came into effect as also even under the new definition of 'manufacturer', Wockhardt does not fall within the purview.

- The impugned Price Fixation Notification and impugned Order are therefore contrary to the mandate of the provision of DPCO, 2013.

(v) Further they submitted that the company is almost the sole manufacturer of the drug and its existing price has not been considered.

- They are buying this product from Emil Pharmaceutical Industries Pvt. Ltd. at Rs. 41.82 per pack of 10 tablets. Whereas their selling price at above notified price if at all after the aforesaid notification after adjusting stockiest and chemist margin will be Rs. 32.63 which is way below the current cost price.

- They request the Department to direct NPPA to withdraw the notification related to above formulations.

5. A copy of the review petition was sent to the NPPA, which submitted its comments vide its letter dated 27.4.2016, as under:

(i) A complaint was filed in NPPA on 16.02.2015 in which it was informed that M/s Wockhardt Ltd. had launched Methyldopa Tablet 500mg. The same was endorsed by M/s Wockhardt Ltd. vide its letter dated 28.02.2015 that they had started manufacturing Methyldopa Tablet 500mg in December, 2013 and launched in March, 2014 with MRP Rs. 160 per pack of 10's tablets. The same was endorsed by Pharma Trac data vide email dated 31.3.2015. The formulation is manufactured by M/s Medibios Laboratories Pvt. Ltd., and marketed by M/s Wockhardt Ltd. as per the photocopy of formulation pack and as per Form-II submitted in NPPA. Launching of Methyldopa Tablet 500mg after DPCO, 2013, falls in the definition of 'New Drugs' under para 2(u), for existing manufacturers. Therefore, NPPA discussed this case in 24th &

27th Authority meeting and approved the retail price Rs. 4.46/tablet vide S.O. 1254(E) dated 29.3.2016 under para 5 of DPCO, 2013 on the basis of formula given Pronob Sen Committee and the same was also recommended by the Standing Committee under para 15 of DPCO, 2013.

(ii) Launching of New Drug without price approval attracts the provision of overcharging under DPCO, 2013. Therefore, case was referred to Overcharging Division for taking necessary action in this regard.

(iii) Company's request to withdraw the notification related to this formulation has no merit.

6. The contentions of petitioner and the NPPA were heard on 29.4.2016, wherein the petitioner company, in addition to their written submission, further informed that they are getting the product i.e. Methyldopa Tablet 500 mg from Emil pharmaceuticals and not from M/s Medibios Lab. Pvt. Ltd. as mentioned in NPPA SO No. 1254(E) dt. 29.3.2016 and as such the said notification is not applicable in the instant case. They also contended that since they are not the existing manufacturer of Methyldopa 500 mg tablet, the price fixation under para 15(2) of DPCO 2013 is not applicable in the instant case. The petitioner also informed that Methyldopa 500 mg was included in the Schedule I of DPCO 2013 on 10.3.2016. However, the price was fixed by NPPA on 29.3.2016 treating it as a new drug whereas it should have been fixed under para 6 of DPCO 2013.

In reply to the above submission of the Petitioner Company, NPPA representative mentioned that Wockhardt in their letter dated 5.4.2016 claimed that they had neither manufactured or imported or marketed scheduled formulation of Methyldopa of any strength or dose including 250 mg which is a scheduled formulation as per DPCO 2013. However, NPPA stated that they had a copy of the periodicals magazines like IDR, MIMS indicating the presence of Wockhardt's instant pack under their brand in the pharmaceutical market, which were submitted to the reviewing authority. NPPA has also received a complaint that M/s Wockhardt has launched Methyldopa 500 mg tablet in March 2014 with MRP Rs.160/- per pack of 10

tablets. The formulation is manufactured by M/s Medibios Lab. Pvt. Ltd. and marketed by M/s Wockhardt Ltd. Keeping this fact in view it is clear that Methyldopa 500 mg tablet is a new drug for M/s Wockhardt and they were supposed to submit form I application to get the retail price from NPPA but M/s Wockhardt did not submit form I application and started to market Methyldopa 500 mg tablet without price approval which attracts the provision of overcharging under DPCO 2013. Petitioner denied that Methyldopa 250mg tablet referred by NPPA is their product. They contended that data sourced by NPPA is not correct. The Petitioner mentioned that they will substantiate their statement with data and facts available with them.

NPPA further submitted that NPPA is empowered under DPCO 2013 issued under Section 3 of EC Act to fix and regulate price of all formulations/medicines including non scheduled as per para 19, 20, 25 and 26 of DPCO 2013. Price fixation cases of new drug which were launched in the market without price approval the Authority and was of the opinion that recovery of entire amount of sale proceeds as overcharged amount from the company as per the provision of para15(5) of DPCO 2013 will be made from the company. This case was again discussed in 27th Authority Meeting of NPPA and retail price of Rs.4.46 per tablet was fixed vide SO 1254(E) dt. 29.3.2016 as per the recommendation of Standing Committee of Experts. When the ceiling price of Methyldopa 250 mg. was fixed @ Rs.1.69 per tablet vide SO 3129 (E) dt. 10.12.2014, to market 500mg tablet @ Rs.16 per tablet is not rational and justified. Since this Methyldopa 500 mg tablet is included in NLEM 2015 ceiling price for this pack will be fixed by NPPA in ensuing meetings of the Authority.

7. In the review meeting held on 31.5.2016, the petitioner company submitted that they have furnished the requisite details with regard to the Methyldopa Tablet 500 mg. vide their letter, dated 5th May, 2016. The petitioner company contended that consequent upon inclusion of Methyldopa 500 mg in scheduled drug as per NLEM 2015, the ceiling price of the product should be fixed in terms of para 6 of DPCO, 2013 instead para 5, because it is not a new drug under para 2(u) of the DPCO, 2013. Accordingly the price cannot be fixed as a new drug. NPPA

representative mentioned that the matter is under examination and will be placed before the Authority Meeting as per provisions of DPCO, 2013 for a decision. NPPA representative was advised to sort out the issue expeditiously.

8. During the hearing on 18.10.2016, the company reiterated its earlier stand that they have neither been manufacturing nor marketing Methyldopa Tablet 250 mg. The company is manufacturing and marketing only Methyldopa Tablet 500 mg. The company amply substantiated their claim by providing copy of product sample of Methyldopa 250 mg. tablet, which clearly indicate the subject product is that of Tridoss Laboratories Pvt. Ltd. The company has further reiterated that M/s Wockhardt has neither manufactured, imported/ marketed Methyldopa 250 mg. tablet. The company prayed for an early decision and direction to NPPA for refixing the price of Methydopa 500 mg. as a scheduled formulation, as it does not come under the definition of new drug under para 2(u) of DPCO, 2013.

9. The NPPA representative submitted that the issue regarding whether the product Alphadopa 250 mg. has been manufactured / marketed by M/s Wockhardt was arisen with the receipt of complaint on March, 2015. From the copy of samples for the month of November, 2015 and January, 2016, received from M/s Wockhardt, it was observed that this product was manufactured by M/s Medidios Laboratories Pvt. Ltd. and marketed by M/s Tridoss Laboratories Pvt. Ltd., and not by M/s Wockhardt Ltd. The NPPA representative submitted that their M&E Division also could not provide any documentary proof that Alphadopa 250 mg. was being manufactured / marketed by M/s Wockhardt Ltd.

10. **Examination:**

The company reiterated its earlier stand that they have neither been manufacturing nor marketing Methyldopa Tablet 250 mg. The company is manufacturing and marketing only Methyldopa Tablet 500 mg. The company amply

substantiated their claim by providing copy of product sample of Methyldopa 250 mg. tablet, which clearly indicate the subject product is that of Tridoss Laboratories Pvt. Ltd. The company has further reiterated that M/s Wockhardt has neither manufactured, imported/ marketed Methyldopa 250 mg. tablet.

It was further informed by NPPA that the issue regarding whether the product Alphadopa 250 mg. has been manufactured / marketed by M/s Wockhardt was arisen with the receipt of complaint on March, 2015. From the copy of samples for the month of November, 2015 and January, 2016, received from M/s Wockhardt, it was observed that this product was manufactured by M/s Medidios Laboratories Pvt. Ltd. and marketed by M/s Tridoss Laboratories Pvt. Ltd., and not by M/s Wockhardt Ltd. The NPPA's representative submitted that their M&E Division also could not provide any documentary proof that Alphadopa 250 mg. was being manufactured / marketed by M/s Wockhardt Ltd.

In view of the facts of the case, it is clear that the NPPA could not substantiate the complaint received by them in March, 2015, based on which the NPPA treated Methyldopa 500 mg tablet as a new drug and fixed the retail price under para 15 of DPCO,2013. The company submitted the documentary proof that they are manufacturing and marketing only Methyldopa Tablet 500 mg., which is a "scheduled drug" under NLEM, 2015, and claimed that there is no competitor of the subject formulation.

Keeping in view above facts, the Hearing Authority is of the view that the ceiling price of the subject formulation should be fixed as per para 6 of DPCO, 2013. Therefore, NPPA may be directed to re-examine the fixation of price of Methyldopa 500 mg. tablet and to re-fix the ceiling price under para 6 of DPCO, 2013.

11. **Government decision:**

"NPPA is hereby directed to re-fix/revise the ceiling price of the formulation Methyldopa 500 mg. tablet as per para 4(1) and para 6 of DPCO,2013, based upon the statistical and documentary proof, submitted by the petitioner company, i.e. M/s Wockhardt Ltd. and any other relevant information/data on merit within a period of one month from the date of issue of the Order of Reviewing Authority."

In view of the above, the present review petition stands disposed off.

Issued on this 5th day of January 2017.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. M/s. Wockhardt Limited,
   Wockhardt Towers,
   Bandra Kurla Complex,
   Mumbai-400051.
2. The Member Secretary,
   National Pharmaceutical Pricing Authority,
   YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website